Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

The role of endolaryngeal surgery (with or without laser) versus radiotherapy in the management of early (T1) glottic cancer.

Bibliographic Source(s)

Yoo J, Lacchetti C, Hammond A, Gilbert R, Head and Neck Cancer Disease Site Group. The role of endolaryngeal surgery (with or without laser) versus radiotherapy in the management of early (T1) glottic cancer. Toronto (ON): Cancer Care Ontario (CCO); 2012 Mar 14. Various p. (Evidence-based series; no. 5-2). [52 references]

Guideline Status

This is the current release of the guideline.

The EVIDENCE-BASED SERIES report, initially the full original Guideline, over time will expand to contain new information emerging from their reviewing and updating activities.

Please visit the Cancer Care Ontario Web site for details on any new evidence that has emerged and implications to the guidelines.

Recommendations

Major Recommendations

For patients with early (T1) glottic cancer, recommended treatment options include the equally effective endolaryngeal surgery, with or without laser, or radiation therapy. The choice between treatment modalities should be based on patient and clinician preferences and general medical condition.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Early (T1) glottic cancer

Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

Clinical Specialty

Oncology

Otolaryngology

Radiation Oncology

Surgery

Intended Users

Physicians

Guideline Objective(s)

To evaluate, in patients with early (T1) glottic cancer, the role of endolaryngeal surgery (with or without laser) versus radiation therapy, in terms of survival, locoregional control, laryngeal preservation rates and voice outcomes

Target Population

Adult patients with previously untreated early (T1) glottic cancers

Interventions and Practices Considered

1. Endolaryngeal surgery, with or without laser
2. Radiation therapy

Major Outcomes Considered

- Survival rates (overall, disease-free, and cause-specific)
- Locoregional control rates
- Laryngeal preservation rates
- Voice outcomes

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Strategy

The literature was searched using MEDLINE (OVID: 1996 through December Week 4, 2010), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations (January 10, 2011), EMBASE (OVID: 1996 through January 2011, Week 1), and the Cochrane Library (OVID: 4th Quarter 2010). In addition, the proceedings of the meetings of the American Society of Clinical Oncology (ASCO), the American Society of Therapeutic Radiology and Oncology (ASTRO), and the Canadian Association of Radiation Oncology (CARO) were all searched for relevant abstracts in the years 2007 to the most recently available, 2010. Reference lists of studies deemed eligible for inclusion in the systematic review were scanned for additional citations.

The literature search of the electronic databases combined disease-specific terms (squamous cell carcinoma, cancer, malignancy, neoplasm, tumour) along with site-specific terms (larynx, vocal cord, glottis, subglottic, supraglottic) and treatment-specific terms (irradiation, radiotherapy, surgery, endoscopic surgery, microsurgery) for all study designs (Appendix 2 in the original guideline document).

In addition to this search of the electronic databases, an Internet search of Canadian and international health organizations and the National Guidelines Clearinghouse was conducted for existing guidelines and systematic reviews relevant to our research question. Guidelines were included if they were published since 2006 in English. This environmental scan yielded three practice guidelines and one consensus statement. The Working Group of the Head and Neck Cancer Disease Site Group (DSG) decided that proceeding with a new systematic review that includes the latest research was warranted, given the time elapsed or lack of reporting of the literature included in these practice guidelines.

Study Selection Criteria

Inclusion Criteria

Articles were eligible for inclusion in this systematic review of the evidence if they were the following:

- Abstracts or full reports of randomized trials or non-randomized comparative studies that evaluated endolaryngeal surgery, with or without laser, and radiation therapy in the primary treatment of early (T1) glottic cancer.
- Reports of systematic reviews or evidence-based guidelines with systematic reviews that addressed the guideline question.
- Retrospective or cross-sectional studies that included a minimum of 50 patients.
- Studies including patients with greater than T1 disease if the majority of patients had T1 disease and if the outcome of interest was other than post-treatment voice quality.
- Studies reporting at least one of the following outcomes: survival, local or locoregional control, larynx preservation rate, or post-treatment voice quality.

Exclusion Criteria

Articles published in languages other than English were excluded because of limited translation resources.

Number of Source Documents

A total of 1,045 studies were identified in the complete literature search, of which 146 were pulled for full-text review. The two systematic reviews, one with a meta-analysis, and 17 primary studies that met the inclusion criteria are included in this review.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Quality Appraisal

Systematic reviews and meta-analyses were assessed for quality using the Assessment of Multiple Systematic Reviews (AMSTAR) tool. The quality of primary studies included assessments for study design, type of data collection, balance between the treatment groups, differences in baseline patient characteristics, and reporting of such differences.

Synthesizing the Evidence

If clinically homogenous data from two or more studies are available, the data will be pooled using the Review Manager software. Pooled adjusted hazard ratios (HRs) for survival would be obtained using a random effects model. The presence of statistical heterogeneity would be evaluated using the x^2 test for heterogeneity and the I^2 percentage. A probability level for the x^2 statistic less than or equal to 10% ($p \leq 0.10$) and/or an I^2 greater than 50% would be considered indicative of statistical heterogeneity.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This evidence-based series (EBS) was developed by the Head and Neck Cancer Disease Site Group (DSG) of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO), use the methods of the Practice Guidelines Development Cycle. For this project, the core methodology used to develop the evidentiary base was the systematic review. Evidence was selected and reviewed by two members of the PEBC Head and Neck Cancer Disease Site Group (DSG) (see Appendix 1 for a complete list of DSG members) and one methodologist.

The series is a convenient and up-to-date source of the best available evidence on the role of endolaryngeal surgery (with or without laser) versus radiotherapy in the management of early (T1) glottic cancer, developed through review of the evidentiary base, evidence synthesis, and input from external review participants in Ontario.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Published cost analyses were reviewed

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Report Approval Panel Review and Approval

Prior to the submission of this evidence-based series (EBS) draft report for External Review, the report was reviewed and approved by the Program in Evidence-based Care (PEBC) Report Approval Panel, a panel that includes oncologists and whose members have clinical and methodological expertise.

External Review by Ontario Clinicians and Other Experts

The PEBC external review process is two-pronged and includes a targeted peer review that is intended to obtain direct feedback on the draft report from a small number of specified content experts and a professional consultation that is intended to facilitate dissemination of the final guidance report to Ontario practitioners.

Following the review and discussion of Section 1: Recommendations and Section 2: Evidentiary Base of this EBS and the review and approval of the report by the PEBC Report Approval Panel, the Head and Neck Cancer Disease Site Group (DSG) circulated Sections 1 and 2 to external review participants for review and feedback.

Methods

Targeted Peer Review

During the guideline development process, six targeted peer reviewers from Ontario and Alberta, considered to be clinical and/or methodological experts on the topic, were identified by the working group. Several weeks prior to completion of the draft report, the nominees were contacted by email and asked to serve as reviewers. Three reviewers agreed and the draft report and a questionnaire were sent via email for their review. The questionnaire consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a guideline. Written comments were invited. The questionnaire and draft document were sent out on August 25, 2011. Follow-up reminders were sent at two weeks (email) and at four weeks (telephone call). The Head and Neck DSG reviewed the results of the survey.

Professional Consultation

Feedback was obtained through a brief online survey of health care professionals who are the intended users of the guideline. All Head and Neck professionals from Ontario in the PEBC database were contacted by email to inform them of the survey. Participants were asked to rate the overall quality of the guideline (Section 1) and whether they would use and/or recommend it. Written comments were invited. Participants were contacted by email and directed to the survey website where they were provided with access to the survey, the guideline recommendations (Section 1) and the evidentiary base (Section 2). The notification email was sent on January 23, 2012. The consultation period ended on March 5, 2012. The Head and Neck DSG reviewed the results of the survey.

Conclusion

This EBS report reflects the integration of feedback obtained through the external review process with final approval given by the Head and Neck DSG and the Report Approval Panel of the PEBC.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are supported by systematic reviews, one with a meta-analysis, and 17 primary studies.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- No statistically significant differences in overall survival or disease–free survival were detected. One retrospective cohort study did report a

significant (p=0.003) 15-year cause-specific survival benefit in surgically treated patients (100%) over those treated with radiation therapy (91%). This result was not consistent with four other retrospective cohort studies that also considered cause-specific mortality and showed no significant differences. The meta-analysis detected no statistically significant laryngectomy-free survival benefits associated with laser surgery when compared to radiation therapy (odds ratio [OR], 0.73; 95% confidence interval [CI], 0.39-1.35).

- One meta-analysis found no statistically significant difference in local control between radiation therapy and laser surgery (OR, 0.66; 95% CI, 0.41 to 1.05). One of eight retrospective cohort studies reported a marginally significant better control rate in surgically treated patients (89%) over those treated with radiotherapy (75%) when only T1a patients were considered (p=0.05). One retrospective cohort study also reported a significant difference in recurrence rates favouring surgery. The same study found a recurrence rate of 30.5% in those undergoing radiation therapy versus 9.9% in the patients treated with laser excision (p=0.001). The remaining five studies did not report any such significant differences in recurrence rates between treatment groups.
- Laryngeal preservation rates were found to be better with surgery, (with or without laser) as compared to radiation in five studies, while one study found a marginally significant better preservation rate with radiation therapy (p=0.051).
- Post-treatment voice and speech quality was assessed by clinician perceptual analysis in one retrospective cohort study, which found that the difference between radiation therapy patients and those treated surgically did not reach statistical significance. In five studies that analyzed patient self-perception, three found no statistically significant difference between treatment groups, one found radiation therapy patients scored significantly better, and one study reported surgically treated patients scored better. One meta-analysis found conflicting results. It detected significantly better maximum phonation time and fundamental frequency in the radiation therapy patients but reported that the perturbation measures of jitter and shimmer significantly favoured the patients undergoing transoral laser surgery.

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- There is currently no well-designed, prospective, randomized controlled trial (RCT) that compares endolaryngeal surgery and radiation therapy. Thus, these recommendations are based primarily on other comparative study designs. Although not substantiated by the evidence, several factors are important considerations when deciding between surgery and radiotherapy for early glottic cancer. Location of disease is one factor. Anterior commissure involvement may be a factor that favours a recommendation of radiotherapy over surgery due to a common opinion that voice outcomes are particularly affected. Tumours localized to the midportion of the vocal fold, and where endoscopic accessibility is uncompromised, may be considered ideal candidates for surgery. Other important practical considerations include the ability for patients to tolerate a general anaesthetic, which is required for surgery. In contrast, radiotherapy requires patient cooperation for daily treatment for four to six weeks. Partial laryngeal surgery, including revision endoscopic surgery, is possible for local recurrence following surgery. However, re-irradiation is not an option in cases of recurrence.
- Care has been taken in the preparation of the information contained in this report. Nonetheless, any person seeking to apply or consult the report is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding the report content or use or application and disclaims any responsibility for its application or use in any way.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report

Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Mar 14

Guideline Developer(s)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

Source(s) of Funding

The Program in Evidence-Based Care (PEBC) is a provincial initiative of Cancer Care Ontario supported by the Ontario Ministry of Health and Long-Term Care through Cancer Care Ontario. All work produced by the PEBC is editorially independent from its funding source.

Guideline Committee

The Program in Evidence-Based Care (PEBC) Head and Neck Cancer Disease Site Group (DSG)

Composition of Group That Authored the Guideline

For a current list of past and present members, please see the Cancer Care Ontario Web site .

Financial Disclosures/Conflicts of Interest

None declared

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

Availability of Companion Documents

The following is available:

- Program in evidence-based care handbook. Toronto (ON): Cancer Care Ontario (CCO); 2011. 15 p. Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on June 11, 2013.

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